

unilimb flexible respiratory conduit is operatively attachable to said housing for use and detachable therefrom after use for independent disposal or sterilization via said proximal fitting.

REMARKS

Claims 13-21 are pending. Counsel for the Applicants thanks Examiner Weiss for the courtesy extended during recent phone calls and for agreeing to have an interview with applicants to discuss the distinctions between the cited Dryden patent and the present claims so as to expedite prosecution. A Request for Continued Examination is submitted herewith so that this amendment and the prior amendment, inclusive of claim 21, may be entered and fully considered. It is respectfully submitted that claims 13-21 are allowable and that the case is in condition for allowance. It is requested that this case be acted upon subsequent to the proposed interview in the event the Examiner does not promptly grant a Notice of Allowance, which would moot the purpose of the interview.

The specification has been amended at page 34 to more expressly state what is taught therein, i.e., that the multilumen filter can act as a proximal fitting. It is respectfully submitted that this does not constitute new matter as the Figures and language of the specification as originally filed clearly teach that the multilumen filter can act to connect a proximal terminal with multiple flexible respiratory conduits.

Drawings: It is respectfully submitted that the filter located in the proximal fitting recited in claims 15 & 16 is shown *inter alia* in Figure 4, part 90, Figures 6A & 6B, parts 158 and 168, Figure 11, part 190, and Figure 22, part 360. It is respectfully noted that the specification teaches that a multilumen filter of the present invention may be used as a multilumen proximal fitting, see for example page 12, lines 18-24, and page 34, lines 2-6. Therefore, It is requested that the objection to the drawings be withdrawn.

Specification: It is respectfully submitted that this objection should be withdrawn for the same reason as the objection to the drawings set forth above.

Claim Rejections:**35 USC §112**

It is respectfully submitted that the rejection of claims 13 -20 should be withdrawn for the same reason as the objection to the drawings set forth above.

It is respectfully submitted that the amendment to claim 13 overcomes the rejection of claims 13-17.

35 USC §102

Claims 13-14 and 17-20 are rejected over U.S. Patent 5,284,160, to Dryden.

Dryden Does Not Disclose the Claimed Inventions and Teaches Away

It is respectfully submitted that the Dryden patent does not teach or suggest a multilumen proximal fitting for a unilimb multilumen circuit as claimed. Dryden's invention is directed to adding a sampling tube to a multilumen anesthesia circuit. Dryden does not teach a multilumen proximal fitting that can be attached and detached by a user at a site of use to a mating multilumen proximal terminal. Circuits constructed with the present invention can be readily constructed and disassembled by a user at the site of use with a simple one-handed motion. In contrast, Dryden's circuit cannot be disassembled by a user at a site of use for independent sterilization or disposal of a multilumen proximal fitting from a mating multilumen proximal terminal. Further, it is respectfully submitted that one of skill in the art would not interpret Dryden as teaching that Dryden's adaptor would be constructed for use and disassembled after use by a user at a site of use by forming and deforming the swivel.

Dryden teaches away from a user disassembling his adaptor device at a site of use by teaching that the sampling tube is fixedly bonded in the proximal part of the adaptor ("machine end connector 41") by a solvent seal (col. 5, lines 18-19). The swivels are included in the Dryden device specifically because it is a unitary circuit with parts bonded together "by use of a solvent seal," as taught for example at column 5, lines 34-39.

In the absence of the swivels in the Dryden's "machine adapter," twisting of the gas conduits could lead to kinking and blockages as the conduits are bonded to the machine adapter. Such obstruction could cause hypoxia to a patient, leading to death

or serious harm. In the alternative, such twisting or tension could lead to unintended and undetected disconnection of the circuit during use, a highly undesired result. That such disconnection is undesirable is well known in the art from use of the devices referred to in column 1 of Dryden, such as U.S. Patent No. 3,856,051 to Bain, and from the patents considered in the Dryden prosecution and listed on its cover page, such as Fukunaga, U.S. Patent 4,265,235 (Dr. Fukunaga is the first named inventor in this case).

The teachings of U.S. Patent 4,265,235 are embodied in the Universal F[®] circuit, which is a unilimb respiratory circuit sold by King Systems Corporation ("King"). King has taken a license to the present invention, and has rights in the cited Dryden patent as well. The proximal terminal of the Universal F[®] is permanently bonded to two flexible respiratory conduits to form a unitary bonded multilumen circuit. The Universal F[®] proximal terminal is not permanently bonded to an assisted ventilation machine as suggested by the Office Action, but is disposed of with the entire circuit after use. There is no teaching or suggestion of a proximal fitting for detachably connecting the flexible conduits to the proximal terminal.

The cited Dryden patent teaches only tubing permanently fixed or bonded to a machine adaptor. Dryden also teaches away from replacing the adaptor with a multilumen proximal fitting and mating multilumen proximal terminal, wherein the proximal fitting can be attached and detached by a user at a site of use to the proximal terminal, because disassembly of Dryden's adaptors would create an unsafe device that could not readily be reconnected in a safe fashion with substantially fluid tight seals between components.

One of ordinary skill in the art of constructing respiratory circuits would be aware of, and would follow, industry guidelines and standards, for example applicable ISO standards, such as ISO 5356-1, previously submitted (A66). These standards call for attachable/detachable tubular connections to have smooth tapered fittings, not the interlocking bent flanges of Dryden's swivels. Since industry standards call for attachable and detachable tubular connections to have smooth tapered fittings, one of ordinary skill in the art would not interpret Dryden's swivels to be formable and deformable by a user at a site of use. Further, Dryden does not teach connection of a

multilumen fitting to a mating multilumen proximal terminal from which it can be disconnected by a user at a site of use. Dryden does not recognize the problems solved by the present invention, much less enable the solutions. Dryden is directed to a different problem, adding a sampling tube to a multilumen conduit, but this is not enabling for the present invention, and in fact, Dryden's solution is contrary to the present invention as it specifically teaches at column 2, lines 40-46, bonding of his adaptor components and tubing together (emphasis and [comment] added):

Hoses for a unilimb breathing system may become twisted by torquing of the hose between the patient and machine. Therefore, swivels which allow the remainder of the device to remain stationary [i.e., fixed or bonded together] while the hose connectors are free to rotate are helpful in order to eliminate torquing and to retain unobstructed airways.

Clearly, one of skill in the art would not consider the components forming the swivels of Dryden to be designed for forming the swivel connection and destroying the swivel connection at the site of use, particularly considering the rushed, crowded, and life and death circumstances usually surrounding the use of respiratory circuits and existing standards. In other words, the swivel connection would be interpreted by one of ordinary skill in the art to be designed for its swivelling function, not for disconnection and reconnection. Trying to assemble and disassemble the swivel connections of Dryden at the site of use is simply not medically, much less, technically feasible, and would still not achieve the present invention. The other patents cited, U.S. Patents No. 6,415,789, No. 6,209,539, and No. 4,676,241, do not make up for the other deficiencies in the prior art; they are directed to connection of single lumen, not multilumen, fittings, and the first two are not prior art as they are filed after the application upon which priority is claimed.

One of Skill In the Art Would Interpret Dryden to Teach a Unitary Bonded Circuit

Applicants' current application introduces to the breathing circuit art the concept of a multilumen proximal fitting for use with a multilumen proximal terminal, wherein the proximal fitting can be attached and detached from the proximal terminal by a user at the site of use for independent sterilization and/or disposal. The proximal fitting and proximal terminal are defined in Applicants' specification, e.g., see paragraph bridging

pages 7 & 8, first full paragraph of page 13, and pages 19-23. The present inventions provide significant and unexpected improvements over prior art unilimb circuits, such as improved safety with reduced manufacturing and respiratory care/anesthesia costs. The prior art does not teach or suggest a multilumen proximal fitting, and teaches away from making an independent proximal terminal which could take advantage of the proximal fitting of the present invention. Thus, the prior art would lead one of ordinary skill in the art to interpret Dryden to teach a unitary bonded circuit.

Examples of prior art patents that teach away from an independent proximal terminal in multilumen unilimb breathing circuits include U.S. Patent 3,856,051, U.S. Patent 4,007,737, and U.S. Patent 4,265,235 to Dr. Atsuo Fukunaga, and U.S. Patent 4,637,384, all of which are cited on the cover of the cited Dryden patent. These patents contain numerous teachings of why it was considered necessary to firmly adhere the flexible patient respiratory conduits to the machine adaptor, wherein the entire circuit, tubing and machine adaptor bonded thereto, is disposed of after use. For example, U.S. Patent 4,367,769, to Bain, at column 1, lines 23-37, states ([comments] added):

It is the fact of this connection [i.e., machine adaptor or proximal terminal] that has proved to be a considerable problem...The second flexible tube [i.e., fresh gas carrying inner tube] connected to the elbow has on occasion become disengaged whereby the anesthetic gas spills into the confines of the first flexible tubular member [i.e., the outer tube] to the detriment of the patient. Due to the fact that the connection to the elbow with the second flexible tubular member is internally with respect to the rigid tubular connector, one cannot visually inspect the device to determine whether the aforementioned internal connection is still in engagement.

Therefore, those of skill in the art concluded that it was necessary to carefully bond all of the components of a respiratory circuit together, i.e., the machine adaptor was bonded to the flexible conduits running to the patient.

U.S. Patent 4,637,384, to Schroeder, column 1, lines 23-37, states:

One difficulty with the coaxial circuit, particularly in anesthesia breathing circuits, is the assurance of the integrity of the inhalation circuit. Since the inner tube carries fresh gas to the patient or, in the case of an anesthesia circuit, the anesthetic with fresh gas, it is extremely important for the attending personnel to be immediately aware of an inadvertent disconnection.

At the machine end, a disconnection of the inner tube can escape immediate attention, since its view is shielded by the surrounding corrugated outer tube. Thus, it is possible for the inner tube to be disconnected, yet the overall coaxial circuit has the appearance of being completely intact. The potentially dangerous situation of rebreathing exhaled gases is created, which can result in hypoxia and CO₂ buildup in the patient.

Other prior art teachings reinforced the concept that respiratory conduits need to be firmly connected in a circuit. For example, Hannallah et al, assigned reference number A49 in the Information Disclosure Statement submitted August 15, 2002, reported the hazards associated with disconnection of the respiratory conduit from the machine end connector.

In view of the foregoing, it would be unreasonable for one of skill in the art to interpret Dryden to teach anything but a unitary bonded circuit, as (1) Dryden is directed to a circuit with a sampling tube BONDED into its machine adaptor, wherein the purpose of Dryden's swivels is to avoid twisting of the flexible conduits due to the permanent connection of the circuit components together, and (2) the prior art cited in the Dryden patent teaches the danger of detachment of circuit components. There is nothing in Dryden to teach or suggest forming and breaking the connection formed by the swivels, much less how one could do this in a fashion to maintain circuit integrity. It is difficult to imagine how an inner swivel, such as 35B, could be formed by a user at a site of use in view of the spacers 22G and 22H barring access to fingers and/or tools; certainly, there is no teaching or suggestion of such a formation technique or tools because Dryden's circuits are intended to be kept in one piece, and disposed of as one piece after use. Further, Dryden's machine end connector 41 is not a multilumen proximal terminal.

Therefore, it is respectfully requested that the rejections based on Dryden be withdrawn.

35 USC §103(a)

Claim 20 is rejected over Dryden. Claims 15 and 16 are rejected over Dryden in view of U.S. Patent 5,715,815 to Lorenzen ("Lorenzen"). It is respectfully submitted that these rejections are moot in view of the arguments above. Further, Lorenzen does not

solve the deficiencies of Dryden as it does not teach placement of a filter in the proximal fitting of a detachable breathing circuit, nor placement of a filter in both the inspiratory and expiratory lumens.

It was not until the present inventions were invented and publicized that those of skill in the art recognized the substantial benefits of a unilimb multilumen proximal fitting that is attachable and detachable to a mating multilumen proximal terminal, such as improved safety with a simpler and less expensive device. As seen from the prior art, including that cited in the Dryden patent, prior to the present invention, it was believed that detachability of the respiratory conduits from the rest of the circuit was extremely unsafe. The substantial benefits of the present inventions and the associated commercial success demonstrate that one of ordinary skill in the art could not reasonably interpret the Dryden patent as suggested in the office action.

King Systems Corporation (King) has rights to the cited Dryden patent and has produced an anesthesia circuit in accordance therewith that does not include a proximal fitting, as the Dryden patent does not disclose one. King also produces the Universal F[®] under a license to the prior patent to Fukunaga. King licensed the present invention, and has achieved commercial success therewith with an embodiment sold as the Universal F2[®]. Only after seeing the application upon which priority is claimed did King produce in accordance with the present invention a Universal F2[®] multilumen proximal fitting that was attachable to and detachable from a new mating Universal F2[®] multilumen proximal terminal by a user at the site of use. Even if solely for the sake of argument, it could be said that a prima facie case of obviousness were made out, a statement with which applicants vigorously disagree, secondary indicia of nonobviousness are abundant and more than adequate to support patentability. The commercial success and many benefits of the present invention show that the present invention solved a long felt need. The present invention is less expensive to produce, less expensive to use, and is much safer, yet reduces medical wastes and shipping and storage costs. Further, the present invention led to surprising improvements in patient care, as new circuit arrangements were made possible, with new components inserted into the circuit between the proximal terminal and the proximal fitting and/or forming part

of the proximal fitting. Had the present invention been obvious, it would have been made a long time ago.

In view of the foregoing, it is respectfully submitted that all bases for rejection have been overcome, and allowance of claims 13-21 is respectfully requested. It is respectfully requested that the Examiner telephone the undersigned to confirm the interview date on April 29 or 30, 2003 in the event this amendment has not led to allowance so that further prosecution can be expedited.

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Date

Respectfully submitted,

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APPENDIX

Below are the amended claims with insertions underlined and deletions in brackets.

13. (twice amended) A multilumen proximal fitting for a multilumen unilimb breathing circuit, [operatively connecting a multilumen patient respiratory conduit to a proximal terminal of an assisted ventilation or anesthesia machine, comprising a multilumen proximal fitting for connecting a unilimb multilumen respiratory conduit to a mating multilumen proximal terminal of an assisted ventilation or anesthesia machine, said fitting] comprising a rigid housing forming at least two independent lumens, said lumens comprising a first lumen and a second lumen each having a proximal and a distal end, wherein said fitting may be operatively attached to a multilumen proximal terminal having first and second ports at the distal end of third and fourth lumens so that, when said proximal ends of said first and second lumens of said fitting are operatively attached to said first and second ports respectively the third lumen and said first lumen both form part of a first flow path that is independent of a second flow path that is formed at least in part by said second lumen and the fourth lumen, wherein said fitting is operatively attachable to and detachable from a mating multilumen proximal terminal by a user at a site of use and can be used to operatively connect a multilumen patient respiratory conduit to a proximal terminal of an assisted ventilation or anesthesia machine.

21. (amended) [A device combination, comprising the interface device of claim 19 and the] The multilumen proximal fitting of claim 13, further comprising an interface device, wherein said fitting can be operatively attached to and detached from said interface device by a user at a site of use, said interface device comprising a rigid housing having [first] third and [second] fourth lumens defining respectively [first] third and [second] fourth flow paths therein, said [first] third and [second] fourth lumens being independent of each other and each having a distal end and a proximal end, said distal ends of said independent lumens converging at a distal end of said housing so as to be capable of simultaneous operative connection to a unilimb flexible respiratory conduit, and wherein said [first] third and [second] fourth flow paths in said housing diverge from

each other proximally of said distal end of said housing so that said proximal end of said [first] third lumen is independently operatively connectable to an inlet for a source of inspiratory gas while said proximal end of said [second] fourth lumen is independently operatively connectable to an expiratory outlet, wherein a unilimb flexible respiratory conduit is operatively attachable to said housing for use and detachable therefrom after use for independent disposal or sterilization via said proximal fitting.